



## EVALUATION OF INDUCTION OF LABOUR IN TERM PREMATURE RUPTURE OF MEMBRANES BY PGE2 GEL VS INTRAVENOUS OXYTOCIN INFUSION

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### ABSTRACT

Premature rupture of membranes (PROM) refers to rupture of fetal membranes prior to onset of regular uterine contractions. It continues to be one of the most vexing issues of obstetrics due to increased maternal and fetal morbidity and mortality due to delayed intervention. A total of 240 women were divided into two equal groups to receive either i.v. oxytocin or intracervical PGE2 gel by odd-even method with the aim to compare induction to delivery interval and maternal and fetal outcome in both groups. They were followed from admission till discharge of the patient after delivery. Induction to delivery interval was found to be more in PGE2 group but maternal and fetal outcomes were comparable in both groups.

**KEYWORDS :** PGE2 gel, i.v. Oxytocin, Premature rupture of membranes (PROM), induction of labour (IOL)

### INTRODUCTION

Premature rupture of membranes at term is described as rupture of membranes prior to the onset of labor at or beyond 37 weeks of gestation. Approximately 8% of term pregnancies are complicated with PROM. Patient with PROM complains of fluid leakage, vaginal discharge, vaginal bleeding, and pelvic pressure without any contractions.<sup>1</sup> A prolonged interval from rupture of membranes to delivery is associated with an increase in the incidence of chorioamnionitis and neonatal sepsis.<sup>2</sup>

The major maternal risk at this gestational age is intrauterine infection. PROM is also associated with unfavourable cervix, dysfunctional labor, increased cesarean rates, postpartum hemorrhage and endometritis in mother.<sup>3</sup>

The neonatal risks associated with PROM include infection, respiratory distress syndrome, hypothermia, hypoglycemia, intraventricular hemorrhage, bronchopulmonary dysplasia, fetal restriction deformities, pulmonary hypoplasia and fetal/neonatal death.<sup>4</sup> Because the risk of intrauterine infection increases with the duration of PROM and induction of labor decreases the risk of chorioamnionitis, without changing the rate of cesarean delivery, as opposed to expectant management.<sup>5</sup>

Management of cases of PROM still remains one of the most difficult and controversial problems in obstetrics.<sup>6</sup> If labor is induced, the method of induction is usually by intravenous administration of oxytocin. Recently, prostaglandins followed by an infusion of oxytocin if necessary, have been used. It is not known which is better method. For women undergoing active management, oxytocin rather than prostaglandin (PG) is the method of choice for most fellows of the Royal Australian and New Zealand college of obstetrician and gynaecologist in Australia.<sup>7</sup>

The Canadian guidelines states vaginal PGE2 may be considered with ruptured membranes at term can be used in the setting of PROM at term. The NICE guidelines goes even further and states "women with PROM at term have for over two decades, derived benefit from the widespread use of vaginal PGE2 to induce labor in this situation and reached a consensus that a vaginal PGE2 regimen is preferred method of induction of labor for women with PROM at term".<sup>8</sup>

Hence, the aim of our study is to evaluate induction of labor in Term premature rupture of membranes with PGE2 (cerviprime gel) versus intravenous oxytocin infusion.

### MATERIALS AND METHODS

This study was approved by the ethical committee of Kasturba Hospital, Delhi where the study was conducted. From January

2021 to June 2022, 240 pregnant women with singleton pregnancies at  $\geq 37$  weeks, Primigravida/ multigravida  $\leq 3$ , Cephalic presentation, Clear leaking Per vaginam, Bishop's score  $\leq 6$ , no cephalopelvic disproportion, reassuring CTG were recruited. Women were excluded from the study if they had previous uterine surgery, contraindications to prostaglandin, Chorioamnionitis, PTPROM, high risk pregnancy like gestational diabetes mellitus, intrauterine death, gestational hypertension, multiple pregnancy etc.

A total of 240 women were assigned into two groups 120 in each group by even odd method to receive either vaginal PGE2 gel or oxytocin infusion.

Group A were induced by PGE2 gel (3g gel/0.5mg dinoprostone) instilled into the posterior fornix of vagina after assessing the Bishop's Score. Bishop score was reassessed after vaginal PGE2 insertion to monitor progress of labour but not before 6 hours to avoid risk of introduction of infection. If cervix is still unfavourable a 2<sup>nd</sup> gel will be instilled, maximum of 3 doses at 6 hours interval in 24 hours. If the patient still not goes in active labour then it was considered as "Failed induction". The side effects of the drug like hyperstimulation (more than 4 contractions in 10 min), tachysystole, fetal distress were observed.

Group B, consisting of 120 patients will be induced by intravenous oxytocin infusion. The infusion was start at the rate of 2mIU/min (synthetic oxytocin consists of 5IU/ml) and then it will be increased at the rate of 1mIU/min at 30 min interval up to maximum dose of 30 mIU/ min. The dose at which patient had achieved the strong uterine contractions (minimum of 3 contractions in 10 min each lasting for 40- 45 seconds) was maintained till delivery and didn't increased further. During the whole infusion procedure, side effects that were observed like tachysystole (>5 contractions per 10 minute period averaged over 30 minutes).

### RESULTS

Demographic characteristics, clinical outcome, maternal and fetal outcomes was summarized in the following tables.

There were no cases of intrapartum chorioamnionitis or postpartum endometritis.

**Table 1: Demographic Characteristics Of Study Population**

	PGE2 (n= 120)	Oxytocin (n=120)	p- value
Maternal age (yr)	25.18 $\pm$ 2.88	24.75 $\pm$ 2.61	0.223
Maternal BMI (kg/m <sup>2</sup> )	23.99 $\pm$ 2.94	24.42 $\pm$ 2.27	0.207
Gestational age (weeks)	38.13 $\pm$ 0.90	38.23 $\pm$ 1.04	0.391
Nulliparous, n (%)	85 (70.83%)	80 (66.7%)	0.486
Multiparous, n (%)	35 (29.1%)	40 (33.3%)	

**Table 2: Clinical Outcomes Of Study Population**

	PGE2 (n= 120)	Oxytocin (n=120)	p- value
Pre-induction Bishop score	3.99 ± 0.65	4.63 ± 0.73	0.001
Bishop score change in 12 hours	7.88 ± 0.88	8.14 ± 0.85	0.029
PROM to Induction (hr)	8.74 ± 3.21	9.52 ± 2.4	0.035
PROM to delivery (hr)	23.18 ± 5.45	20.87 ± 4.47	0.001
Induction to delivery (hr)	14.42 ± 4.3	11.39 ± 3.46	0.001
Repeat second gel, n (%)	62 (51.6%)	0	0.001

**Table 3: Maternal Outcomes In The Study Population**

	PGE2 (n= 120)	Oxytocin (n=120)	p- value
Uterine Tachysystole	5 (4.1%)	4 (3.33%)	0.734
Uterine hyperstimulation	5 (4.16%)	3 (2.5%)	0.472
Vaginal Delivery	91 (75.8%)	97 (80.8%)	0.408
Forceps Delivery	4 (3.33%)	3 (2.5%)	
Cesarean Section	25 (20.8%)	20 (16.6%)	
Fetal distress	15 (60%)	12 (60%)	0.540
Cephalopelvic disproportion	5 (20%)	6 (30%)	0.250
Failed Induction	5 (20%)	2 (10%)	0.758
Maternal Fever	14 (11.6%)	13 (10.8%)	0.838
Postpartum Hemorrhage	2 (1.6%)	2 (1.6%)	1.000
Meconium stained liquor	2 (1.6%)	0	0.156
Need for blood transfusion	2 (1.6%)	2 (1.6%)	1.000

**Table 4: Neonatal Outcomes Of The Study Population**

	PGE2 (n= 120)	Oxytocin (n=120)	p- value
APGAR score at 1 minute	7.74 ± 0.85	7.12 ± 0.95	0.001
APGAR score at 5 minutes	9.06 ± 0.65	8.7 ± 0.74	0.001
Need for Resuscitation	10 (8.3%)	4 (3.3%)	0.105
Need for NICU for < 5 days	10 (8.33%)	18 (15%)	0.108
Need for NICU for ≥ 5 days	4 (3.33%)	2 (1.66%)	0.408
Birth Weight	2.97 ± 0.23	3.12 ± 0.22	0.001
Male	70 (58.8%)	74 (61.6%)	0.598
Female	50 (41.6%)	46 (38.3%)	
Hospital Stay	3.45 ± 1.41 days	3.04 ± 1.11 days	0.013

**DISCUSSION**

Spontaneous labor is acknowledged to start within 24 hours of rupture of fetal membranes before onset of labor in majority of women. However, induction reduces the risk of maternal infection and shortens the delivery time in term PROM. Oxytocin is usually preferred to promote labor in term PROM, it was recently proposed that PGE2 can be administered vaginally to stimulate cervical ripening in term pregnancies complicated with low bishopscores and PROM. PGE2 is an efficacious agent that shortens the time from induction to delivery, improves success rates, and reduces morbidity associated with labor induction.

In the present study, oxytocin infusion significantly shortened the induction to delivery interval when compared with PGE2 gel. PGE2 gel and oxytocin infusion didn't significantly affect the rate of cesarean delivery or indications (20.8% and 16.6% respectively). oxytocin group had more NICU admission than PGE2 group, all other parameters are comparable in both groups.

Peng Chiong Tan et al (2009)<sup>9</sup> conducted study on 114 patients with 57 in each group to estimate effect of concurrent PGE2 plus oxytocin against oxytocin for IOL in PROM. Complications were similar in both groups and rate of caesarean were comparable in two groups (40% and 35.1%).

Cigdem Kunt et al (2011)<sup>1</sup> conducted study on 240 women with 120 in each group to compare the safety and efficacy of between PGE2 and oxytocin for labor induction in term PROM and was found statistically significant in both groups, p=0.02. maternal and fetal outcome was expirable except NICU

admission that was higher in oxytocin group (11.6% vs 16.7%).

Nur Gozde Kulhan et al (2018)<sup>10</sup> conducted study on 224 women with 112 in each group to compare maternal and fetal outcomes in both the groups. Induction to delivery time was longer in PGE2 group, caesarean rates and vaginal delivery was equal in both groups.

**CONCLUSION**

It may be concluded that PGE2 gel appears to be relatively inefficient method of inducing labor when compared with oxytocin in term PROM with unfavourable cervixes. PGE2 may maintain uterine contractions as effectively as oxytocin once contractions are established. But there is no significant difference in maternal and fetal outcomes. As PGE2 is a good cervical ripening plus inducing agent it is rationale to prefer PGE2 gel to induce labor in term PROM with unfavourable cervixes.

**Recommendations**

Women should be educated about possibility of PROM and the need to report at the earliest. It is advisable to develop new scoring strategies involving demographic variables with previous history of PROM to identify high risk cases to treat them prior to rupture of membranes.

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